

REMARKS/ARGUMENTS

Claims 1-38 are pending in this application. Of these pending claims, nos. 22-24 are under examination. These have been rejected. Claims 1-21 and 25-38 are withdrawn from consideration by the Examiner as being directed to non-elected inventions.

In this Amendment claims 23 and 24 are amended to more clearly define, respectively, applicants' diagnostic and pharmaceutical compositions. Furthermore, claim 22 has accordingly been canceled from the application without prejudice or disclaimer. No new matter is added by this response and entry of the proposed claim amendments is, therefore, respectfully requested.

Objections to the Specification

The disclosure is objected to due to the embedded hyperlinks and/or other form of browser-executable code found at pp. 61-62 of the specification.

In response, applicants have amended the specification at the indicated locations in a manner which is believed to overcome the rejection. The Examiner is, therefore, respectfully requested to reconsider and withdraw the objections in light of the indicated amendments.

Claim Objection

On p. 3 of the Office Action claim 22 is objected to for the reasons provided. Claim 22, however, is canceled in this response without prejudice or disclaimer and this cancellation is believed to render moot the Examiner's objection. The Examiner is therefore respectfully requested to reconsider and withdraw the objection to applicants' claims.

Furthermore, the Examiner's comments with regard to 'improving' the clarity of claim 22 have been taken into account in making the amendments to claims 23-24 and the subject claims thus do not include the deficiencies attributed on p. 3 to claim 22.

Claim Rejections Under 35 U.S.C. §112

Claims 22-24 are rejected under 35 U.S.C. §112, first paragraph, for allegedly failing to comply with the 'written description' requirement of the statute (see, e.g., the Office Action at pp. 4-6). Furthermore, the subject claims are additionally rejected (i.e., at pp. 7-8) as also allegedly failing to comply with the 'enablement' requirement of the indicated statute. Still further, at pp. 9-10 the claims are also rejected under 35 U.S.C. §112, second paragraph, as being allegedly indefinite. These grounds for rejection are respectfully traversed.

To begin with, as indicated above claim 22 has been canceled from the application without prejudice or disclaimer, which moots all of the rejections under §112 insofar as they concern the subject claim.

Furthermore, the remaining rejected claims (nos. 23-24) have been extensively amended in a manner which is believed to be entirely responsive to the bases set forth for the above-identified rejections. In particular, in (amended) claims 23-24 as now presented, mention is no longer made of any non-elected invention(s), e.g., an antibody. The various paragraphs/subparagraphs are now more clearly labeled, i.e., as 1(a) - 1(e), 2, 3 and 4 (as suggested by the Examiner in the discussion of the claim objections). Furthermore, the language now contained in the amended claims makes it clear that the subject diagnostic composition (claim 23) and the pharmaceutical composition (claim 24) comprise an agent as defined in the claims and not a substance identified by the agent.

Moreover, further with regard to the rejections directed to an alleged lack of written description and enablement, applicants submit that the written description provided by applicants discloses that Rbp1p, i.e., an "agent" according to (amended) claims 23 and 24, is a necessary factor for producing the virulence of *Candida*, as well as for the successful infection of the host by *Candida* (see, e.g., the specification at p. 49, second paragraph; p. 62, second paragraph; p. 64, first paragraph and Figure 5). Since it has been shown in applicants' description that Rbp1 is required for the

virulence of the fungi in an organism, one having an ordinary level of skill in this field can reasonably conclude that the inactivation of the Rbr1p gene, or gene product, would inhibit its function, i.e., the virulence noted above. One having an ordinary level of skill in the relevant art can thus use, without undertaking any undue experimentation, the nucleic acids and proteins recited in claims 23 and 24 (as amended) for inactivating Rbp1. Thus, one of ordinary skill would, with relative ease, recognize that the written description provided in the specification thoroughly characterizes applicants' presently claimed compositions, as now recited in (amended) claims 23 and 24. Furthermore, such individual would, in applicants' view, find the presently claimed compositions entirely 'enabled' in accordance with the requirements of the statute, and thus it would not require any 'undue experimentation' in order to practice the invention as now recited in the subject claims.

Still further, it is applicants' contention that one having an ordinary level of skill in this field of art can readily determine the homologues and fragments of nucleic acids, according to subparagraphs (c) and (e) in paragraph 1 of claims 23 and 24 without the need to undertake any undue experimentation. That is, applicants submit that, at the time the invention as now claimed was made, it was a routine matter for one having an ordinary level of skill in the relevant field to test the specific 'category' of nucleic acids recited in subparagraphs (c) and (e) in paragraph 1 of claims 23 and 24 using high through-put techniques that were well known to those working in this field at the relevant time.

Based on the reasons set forth above the Examiner is respectfully requested to reconsider and withdraw the rejections under 35 U.S.C. §112, first and second paragraphs, of applicants' claims 23 and 24.

Claim Rejections Under 35 U.S.C. §102

At p. 10 of the Office Action claims 22-24 are rejected under 35 U.S.C. §102(a) as being

allegedly anticipated by Lotz et al., *Eucaryotic Cell* 3(3): 776-784 (2004). The cancellation (without prejudice or disclaimer) of claim 22 renders the rejection moot as to that claim. With regard to claims 23 and 24, however, the rejection is respectfully traversed.

Applicants respectfully submit, however that the Lotz publication is not an effective reference against the claims of their application. That is, the Lotz et al. reference has a publication date of June 2004. In contrast, the present application is a §371 National Stage filing of PCT/EP2005/002748 (filed January 16, 2006) which, in turn, claims the priority of 'parent' German application No. 10 2004 013 826.5 filed on March 16, 2004, i.e., a date which is prior to the publication date of the Lotz et al. reference.

Further with regard to applicants' claim for priority, p. 3 of the Office Action acknowledges the claim and states that a certified copy of the foreign (German) priority document was filed in this case on September 15, 2006. However, the copy is in a non-English language, i.e., German. Thus, at p. 11 of the Office Action the Examiner further states that should applicants present an argument, which they in fact are presenting, that the reference of Lotz et al. cannot be applied in a rejection under 35 U.S.C. 102(a) due to the date of the publication, applicants should provide an English translation of the priority document submitted with the instant application.

In response, applicants note for the Examiner's information that the priority document (i.e., German application No. 10 2004 013 826.5) has the same wording, i.e., without any additions, deletions or modifications as the International Application (PCT/EP2005/0903947) which forms the basis for the present U.S. national filing. The present U.S. application thus differs from the priority document (German 10 2004 013 826.5) only with regard to the amendments set forth in the Preliminary Amendment filed on September 15, 2006 with the present application. In effect, therefore, applicants submit that they have already provided what amounts to an English translation of the priority document submitted with the instant application. Thus, they believe that they are

already in compliance with the Examiner's requirement for a translation of the priority document. If the Examiner does not agree that the requirement has been met, she is respectfully requested to contact applicants' representative, preferably by telephone at the number provided below, and inform said representative as to what additional steps need to be taken to meet the requirements of the Patent Office in this regard, whereupon applicants will comply with any such requirements.

Nevertheless, pursuant to the facts as presented above, the Examiner is respectfully requested to reconsider and withdraw the anticipation rejection under 35 USC 102(a) based on Lotz et al. on the basis that Lotz et al. is not an effective reference against the claims of this application, given that as established above this case is entitled to a priority date that is prior to the publication date of the Lotz et al. reference.

Claim Rejections Under 35 U.S.C. §103

Claims 22-24 are rejected at p. 11 of the Office Action under 35 U.S.C. §103 over Sohn et al., Molecular Biology 47(1), pp. 89-102 (2003) in view of Tsong et al. Cell 115(4), pp. 389-399 (2003) and as evidenced by Lotz et al. The rejection is respectfully traversed.

In response, applicants note that, due to the cancellation (without prejudice or disclaimer) of claim 22, the rejection of the subject claim is, accordingly, moot. Furthermore, claims 23 and 24 reciting, respectively, a diagnostic composition comprising an agent selected from a particular group of materials and a pharmaceutical composition comprised of a corresponding agent, are now extensively amended such that they, accordingly, now clearly recite features of the claimed compositions that are believed to distinguish applicants' inventions from the cited combination of references.

More particularly, neither Sohn et al. nor Tsong et al., whether taken individually or in combination, teach or even suggest to one having an ordinary level of skill in the relevant art that Rbr1p is a membrane protein which is required to produce the virulent effect attributable to *Candida*,

as well as for the successful infection of a host by the *Candida*. Accordingly, such individual would have no means of concluding from Sohn et al. or Tsong et al., when considering their combined disclosures, that the sequence ORF 6.6747 disclosed in both of these references bears any relevance to the virulence of fungi such as *Candida albicans*.

Additionally, as noted by applicants above in the discussion of the anticipation rejection of the subject claims, the Lotz et al. publication is not an effective reference against the present application and, thus, its disclosure can not be relied upon to supplement or supplant the disclosure provided by the combination of Sohn et al. and Tsong et al. It's disclosure, therefore, must be discounted from the present analysis and, thus, it cannot be relied upon to support a contention that one having ordinary skill would be able to know that the DNA microarray disclosed in Sohn et al. contains the ORF 6.6747 sequence.

In sum, therefore, applicants submit that one of ordinary skill in this field would find no motivation in the cited combination of Sohn et al. and Tsong et al. (with Lotz et al. being excluded due to the reasons presented above) to use the sequence ORF 6.6747, or the protein coded by the subject sequence, in a diagnostic or a pharmaceutical composition as presently respectively recited in (amended) claims 23 and 24.

For the reasons above therefore, the Examiner is respectfully requested to reconsider and withdraw the rejection of applicants' claims 23 and 24 under 35 U.S.C. 103.

Respectfully submitted,



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